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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,382	02/24/2004	Shumin Yang	IM-2-C1-C1-1	5307

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HESKA CORPORATION  
INTELLECTUAL PROPERTY DEPT.  
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FORT COLLINS, CO 80525

EXAMINER
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KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/787,382

Applicant(s)

YANG ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response filed on 01/31/05 has been acknowledged.

*Claims 1-18 are canceled.*

*Claims 19-33 are newly filed.*

*Claims 19-33 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.*

### ***Claim Rejections - 35 USC § 112***

Claims 19-20, 24-25 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons of record as set forth in the office action mailed on 09/30/4.

The scope of invention as claimed encompasses any and all variants of nucleic acid sequences that encodes the amino acid sequences of SEQ ID NO: 5, wherein the nucleic acid as claimed encoded a protein comprising at least 20 contiguous amino acid sequences found in SEQ ID NO:5 and the encoded protein binds to an antibody produced against amino acid sequences of SEQ ID NO:5. The scope of invention as claimed further encompass any and all variants of nucleic acid sequences of SEQ ID NO:4, wherein the nucleic acid as claimed comprises at least 45 contiguous nucleic acid

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sequences found in SEQ ID NO:4 and encodes a protein that binds to an antibody produced against amino acid sequences of SEQ ID NO:5. The scope of invention as claimed further encompasses any and all variants of nucleic acid sequences wherein the nucleic acid as claimed is 95% identical to SEQ ID NO:4, SEQ ID NO:7 and SEQ ID NO:9 and the nucleic acid sequence encodes a protein that binds to an antibody produced against amino acid sequences of SEQ ID NO:5. The scope of invention as claimed also encompasses any and all natural and non-natural variant of nucleic acid encoded by SEQ ID NO:5, wherein the nucleic acid is obtained from any and all organisms (other than dog). In addition the scope of invention as claimed encompass a nucleic acid sequence that encodes a canine IL-5 like protein which binds to an antibody produced against a protein having the amino acid sequences of SEQ ID NO:5.

### ***Response to Arguments***

Applicant's arguments filed 01/31/05 have been fully considered but they are not persuasive. Regarding the Written description issues the applicant argues that since the applicants have disclosed the full length sequence of canine IL-5 protein and DNA encoding this protein, all nucleic acid molecules encoding 20 amino acid structure of canine IL-5 and all nucleic acid molecule comprising at least 45 nucleotides identical to the disclosed nucleotides are inherently disclosed. The applicant argues that it would be a simple matter for one skilled in the art to look at the disclosed sequences and synthesize or produce a nucleic acid molecule falling within the scope of the instant claims for the claimed activity.

However, applicant's arguments are found NOT persuasive. The applicant was referred to the guidelines for *Written Description Requirement* published January 5, 2001 in the Federal Register, Vol.66, No.4, pp.1099-1110. The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (see *In re Shokal* 113USPQ283(CCPA1957); *Purdue Pharma L. P. vs Faulding Inc.* 56 USPQ2nd 1481 (CAFC 2000). At best the instant specification as filed teaches the nucleic acid sequence of SEQ ID NO: 18 which encodes the amino acid sequences of SEQ ID NO:5 and 10 (Canine IL-5). The specification fails to disclose any variants of nucleic acid

sequence of SEQ ID NO: 18 or nucleic acid encoding the amino acid of SEQ ID NO: 5 and 10 that has any IL-5 like activity or binds to and antibody produced against the protein of SEQ ID NO:5 explicitly or implicitly as putatively considered by the instant specification. The specification fails to define the minimal structure or consensus core structure that defines the genus comprising nucleotide sequences encoding the amino acid sequences of IL-5. The possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with *sufficient relevant identifying characteristics* (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). In the instant case the nucleic acid variants (as claimed) has been defined only by a statement of function that broadly encompasses an anti-SEQ ID NO:5 (antibody) binding activity, which conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. The variation as claimed also encompasses the conserved motifs, which are considered germane to the functional activity of an IL-5 like polypeptide. For example 5% variation (95% identical) as claimed would certainly affect proper folding and biological activity if amino acids that are critical for such functions are substituted, since the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. Furthermore, mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues (see Ngo, in *The Protein Folding Problem and Tertiary Structure Prediction*, Merz et al. (eds.), Birkhauser Boston: Boston, MA, pp. 433 and 492-495, 1994). Rudinger (in *Peptide Hormones*, Parsons (ed.), University Park Press: Baltimore, MD, pp.1-7, 1976). Furthermore, the scope of invention as claimed encompasses any variant that does NOT even comprise the conserved amino acid

sequences for the required for the IL-5 activity (see claims 19-20 and 24-25). According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claims 19-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acid sequences of SEQ ID NO:4, 7 and 9 which encodes the amino acid sequences of SEQ ID NO:5 or 7, wherein the recombinant protein has Canine IL-5 activity, does not reasonably provide enablement for any and all natural or non natural variants of SEQ ID NO:4, 7 and 9 obtained from any other organism (other than dog). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the same reasons of record as set forth in the office action mailed on 09/30/4.

The scope of invention as claimed encompasses any and all variants of nucleic acid sequences that encodes the amino acid sequences of SEQ ID NO: 5, wherein the nucleic acid as claimed encoded a protein comprising at least 20 contiguous amino acid sequences found in SEQ ID NO:5 and the encoded protein binds to an antibody produced against amino acid sequences of SEQ ID NO:5. The scope of invention as claimed further encompass any and all variants of nucleic acid sequences of SEQ ID NO:4, wherein the nucleic acid as claimed comprises at least 45 contiguous nucleic acid sequences found in SEQ ID NO:4 and encodes a protein that binds to an antibody produced against amino acid sequences of SEQ ID NO:5. The scope of invention as claimed further encompasses any and all variants of nucleic acid sequences wherein the nucleic acid as claimed is 95% identical to SEQ ID NO:4, SEQ ID NO:7 and SEQ ID NO:9 and the nucleic acid sequence encodes a protein that binds to an antibody produced against amino acid sequences of SEQ ID NO:5. The scope of invention as claimed also encompasses any and all natural and non-natural variant of nucleic acid

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encoded by SEQ ID NO:5, wherein the nucleic acid is obtained from any and all organisms (other than dog). In addition the scope of invention as claimed encompass a nucleic acid sequence that encodes a canine IL-5 like protein which binds to an antibody produced against a protein having the amino acid sequences of SEQ ID NO:5. At best the instant specification as filed teaches the nucleic acid sequence of SEQ ID NO: 4, 7 and 9 and amino acid sequences of SEQ ID NO:5 and 10 encoding canine IL-5.

### ***Response to Arguments***

Applicant's arguments filed 01/31/05 have been fully considered but they are not persuasive. Regarding the enablement issues the applicant argues that since the applicants have disclosed the claimed nucleic acid molecules, it would be within the reach of one skilled in the art to make all nucleic acid sequences with 95% identical to the stated SEQ ID. The applicant argues that similarly one skilled in the art could easily look at the disclosed sequences and produce nucleic acid encoding 20 amino acid stretches of canine IL-5 and all nucleic acid molecule comprising at least 45 nucleotides identical to the disclosed nucleotides are inherently disclosed. The applicant argues that applicants are not required to disclose a test using every species covered by the claims since such experimentation would force inventors to carry out a prohibitive number of actual experiments. The applicant argues that it would not require an undue experimentation to practice the invention as claimed.

However, applicant's arguments are found NOT persuasive. The state of the interleukin art at the time of filing teaches that the role of IL-5 in the growth, activation, and survival of eosinophils is complex. IL-5 activates Lyn, Syk, and JAK2 and propagates signals through the Ras-MAPK and JAK-STAT pathways, wherein Lyn, Syk, and JAK2 tyrosine kinases and SHP-2 tyrosine phosphatase are important for eosinophil survival (Adachi et al Am J Physiol Cell Physiol 275: C623-C633, 1998). Thus it is highly unpredictable that the nucleic acid variants as claimed would have any IL-5 like activity. The earlier office action clearly provided the evidence that it is well known in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are

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substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The variants as claimed herein are only hypothetical proteins because no biological function has been established. The mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues. (see Ngo and Rudinger). The scope of invention as claimed encompasses a nucleic acid sequence that encode a protein comprising at least 20 contiguous amino acid sequences found in SEQ ID NO:5 and binds to an antibody produced against amino acid sequences of SEQ ID NO:5. Furthermore the scope of invention as claimed encompasses a nucleic acid sequence that comprises at least 45 contiguous nucleic acid sequences found in SEQ ID NO:4 and encodes a protein that binds to an antibody produced against amino acid sequences of SEQ ID NO:5. Considering the open language claimed herein the scope of invention as claimed encompasses any and all variants of canine IL-5 (natural or non-natural) comprising a region having only 20 contiguous amino acids or 45 contiguous nucleotides sequences.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). In instant case identification of any and all natural and non-natural variants, wherein only 20 contiguous amino acid or 45 nucleotides sequences are identical and the nucleic acid sequence encodes a protein that has IL-5 like activity or binds to an anti-IL-5 antibody is not routine in the art and would certainly require excessive and undue experimentation, since making and testing a point mutation is significantly different from the making and testing a sequences wherein at least 85% amino acids or 92% nucleic acid sequences are not identical (20aa in SEQ ID NO:5 which is 134aa long; 45nt in SEQ ID NO:4 which is 610nt long). The number of possible scenario increase geometrically with increase in percent non-identity. Such making and testing is nothing more than an invitation to further experimentation, since the specification can not be relied on to teach how to make the variants as claimed. One has to engage in extensive making and testing in order to obtain variants that meet the requirements for the claimed IL-5 activity or anti-



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IL-5 antibody binding activity. This is not considered routine in the art and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). Furthermore, it is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), *Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion"*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. Therefore, the applicant has not presented enablement commensurate in scope with the claims.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Sumesh Kaushal  
Examiner GAU 1636



**SUMESH KAUSHAL**  
**PATENT EXAMINER**